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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/613,439	07/11/2000	Andrew H. Cragg, M.D.	034298-069	1758

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EXAMINER

RUHL, DENNIS WILLIAM

ART UNIT	PAPER NUMBER
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3761

DATE MAILED: 12/16/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/613,439

Applicant(s)

CRAGG, M.D. ET AL.

Examiner

Dennis Ruhl

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 09 September 2002.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-9 and 15-65 is/are pending in the application.
- 4a) Of the above claim(s) 1-9, 20, 21 and 42-60 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 15, 23-30, 32-41 and 61-65 is/are rejected.
- 7) ☒ Claim(s) 16-19, 22 and 31 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 11.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

Applicant's amendment of 9/9/02 has been entered. The examiner will address applicant's remarks at the end of this office action.

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

2. Claims 15,23-29,33-39,61,63-65 are rejected under 35 U.S.C. 102(b) as being anticipated by Brenneman et al. (5645566).

With respect to claims 15,23,25-29,33-39,61,63-65, Brenneman discloses a method of facilitating hemostasis as claimed. Brenneman discloses establishing the depth of the blood vessel and loading an introducer with a pledget 74. See column 7, lines 19-22 and column 10, lines 58-59 for the disclosure of compressing and hydrating the pledget. The introducer is loaded over a guidewire. See column 7, lines 28-30 and column 10, lines 60-63. See column 10, lines 45-63 for the disclosure of ejecting the pledget.

With respect to claim 24, the vent is considered to be the opening of the introducer itself, which facilitates the loading of the introducer.

3. Claims 25,27-30,32-34,61-65 are rejected under 35 U.S.C. 102(b) as being anticipated by Janzen et al. (5391183).

With respect to claims 61-65, Janzen discloses a method of facilitating hemostasis as claimed. Janzen discloses loading an introducer (45 or 29) with a

pledget 57. See column 7, lines 61-67 where it is disclosed that the introducer is loaded over a guidewire. Janzen discloses ejecting the pledget as claimed.

With respect to claims 25,27,28,32,33, Janzen discloses a method of facilitating hemostasis as claimed. Janzen discloses loading an introducer 29 with a pledget 57. See column 7, lines 61-67 where it is disclosed that the introducer is loaded over a guidewire. Janzen discloses ejecting the pledget as claimed. Introducer 29 introduces pledget 57 to sheath 45.

With respect to claims 29,30,62, Janzen discloses establishing the depth of the blood vessel by abutting the wall of the blood vessel as claimed. See column 5, lines 10-27 and column 6, lines 57-58.

With respect to claim 34, Janzen discloses the claimed limitation. This is because applicant is attempting to recite the rate of expansion of the claimed pledget when wetted to the expansion of a "dry" sponge material. If a dry sponge material is uncompressed (no expansion is expected because it is dry and uncompressed), the pledget of Janzen will expand more quickly when wetted.

4. Claims 35,37,39-41, are rejected under 35 U.S.C. 102(b) as being anticipated by Fowler (5601602).

With respect to claims 35,37,41, Fowler discloses loading an introducer with a sponge pledget (sleeve 58 is preloaded with pledget 52). Fowler discloses loading the introducer over a guidewire and advancing the introducer through the skin as claimed (see column 6, line 49 to column 7, line 24 and especially the language "The insertion assembly may then be subsequently inserted into the incision along or over the

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guidewire). Fowler discloses loading the introducer with the sponge pledget before advancing the introducer through the skin.

With respect to claim 39,41, Fowler discloses establishing the depth of the blood vessel puncture because Fowler is closing the puncture so its depth has inherently been determined.

With respect to claim 40, Fowler discloses the use of a catheter sheath 14. See column 4, lines 46-49. The use of sheath 14 effectively establishes the depth of the blood vessel puncture because it is inserted into the patient and to the blood vessel being treated.

Allowable Subject Matter

5. Claims 16-19,22,31, are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

6. Applicant's arguments filed 9/9/02 have been fully considered but they are not persuasive.

With respect to the traversal of the Brenneman reference, if Brenneman discloses attaching the pledget to the end of the catheter and then discloses that the catheter (with pledget attached) is placed into the introducer, this satisfies the claimed limitation of loading the introducer with a sponge pledget. The step of inserting the catheter with the pledget attached to the catheter loads the introducer with the pledget. Applicant's only argument with respect to Brenneman is found to be non-persuasive.

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With respect to the traversal of claims 61-65, the language relied upon by applicant for patentability is not found in claims 61-65. The arguments are not commensurate with the scope of claims 61-65 and are non-persuasive.

With respect to claim 25 and the Janzen reference, a pledget 57 is loaded into holder 29. The holder 29 is an introducer because it introduces the pledget into sheath 45. Claim 25 does not require that the introducer be loaded with the pledget before inserting the introducer into the patient. In fact claim 25 does not even recite that the introducer is inserted into the patient at all. Applicant has argued limitations that are not found in claim 25; therefore, the argument is not commensurate with the scope of claim 25.

The argument with respect to claim 35 is moot based on the new grounds of rejection applied to this claim and some of its dependent claims.

7. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Dennis Ruhl whose telephone number is 703-308-2262. The examiner can normally be reached on Tuesday through Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Weilun Lo can be reached on 703-308-1957. The fax phone numbers for the organization where this application or proceeding is assigned are 703-305-3590 for regular communications and 703-305-3590 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0858.

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DR
December 16, 2002



DENNIS RUHL
PRIMARY EXAMINER